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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,105	03/31/2004	James B. Hunt	8627- 431 (PA-5498-RFB)	6585
757	7590	10/24/2006	EXAMINER	
BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610			POUS, NATALIE R	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/815,105

Applicant(s)

HUNT, JAMES B.

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/17/05, 7/26/04.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Specification

Claim 1 objected to because of the following informalities: the recitation in lines 14 and 19 "wherein a first unattached margin whereby..." is unclear. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites for instance: "said first attached area extends peripherally all around said first attached area." It is unclear as to what limitation this statement is referring.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

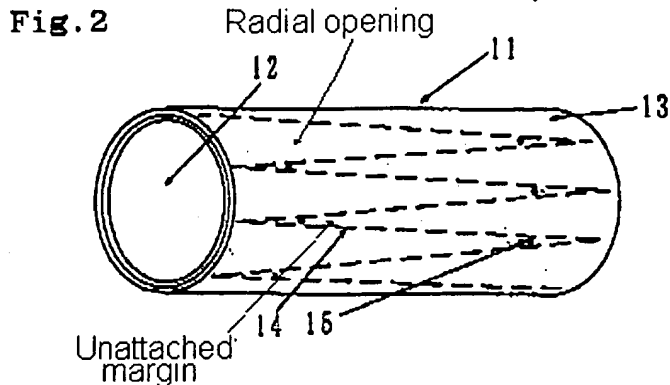
Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuwahara et al. (US 6346119).

Regarding Claim 1, Kuwahara teaches a stent-graft assembly, comprising: a stent structure (14) comprising a luminal surface and an abluminal surface and having

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at least a first radial opening and a second radial opening (see fig. 2 below), said first and second radial openings extending through said stent structure between said luminal surface and said abluminal surface, wherein said first and second radial openings are spaced apart along a first direction; a first graft layer (13) disposed along at least a portion of said luminal surface of said stent structure thereby fully covering luminal sides of said first and second radial openings; a second graft layer (12) disposed along at least a portion of said abluminal surface of said stent structure thereby fully covering abluminal sides of said first and second radial openings (fig. 2); a first attached area (13) securing said first graft layer and said second graft layer together through a portion of said first radial opening, wherein a first unattached margin (see figure 2 below) whereby said first and second graft layers are not secured to each other being disposed between said first attached area and an edge of said first radial opening; a second attached area securing said first graft layer and said second graft layer together through a portion of said second radial opening, wherein a second unattached margin whereby said first and second graft layers are not secured to each other being disposed between said second attached area and an edge of said second radial opening; and wherein said first and second unattached margins are oriented along said first direction (Column 2, proximate lines 19-23), thereby allowing said first and second graft layers to move along said first direction relative to said stent (it is inherent that since the two grafts are only attached at discrete points, the stent is allowed to move relative to the grafts).

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Regarding Claim 2, Kuwahara teaches the stent-graft assembly according to claim 1, wherein a size of said first attached area (15) is less than a size of said first unattached margin and a size of said second attached area (15) is less than a size of said second unattached margin (see fig. 2 above).

Regarding Claim 3, Kuwahara teaches the stent-graft assembly according to claim 1, wherein said first direction is axial (see fig. 2 above).

Claims 1-11, 13, 14 and 16-19 rejected under 35 U.S.C. 102(b) as being anticipated by Lentz et al. (US 5843166).

Regarding Claim 1, Lentz teaches a stent-graft assembly, comprising: a stent structure (28) comprising a luminal surface and an abluminal surface and having at least a first radial opening and a second radial opening (between stent portions 28'), said first and second radial openings extending through said stent structure between said luminal surface and said abluminal surface, wherein said first and second radial openings are spaced apart along a first direction; a first graft layer (22') disposed along at least a portion of said luminal surface of said stent structure thereby fully covering

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luminal sides of said first and second radial openings; a second graft layer (12') disposed along at least a portion of said abluminal surface of said stent structure thereby fully covering abluminal sides of said first and second radial openings (fig. 3); a first attached area securing said first graft layer and said second graft layer together through a portion of said first radial opening (fig. 3), wherein a first unattached margin (30a') whereby said first and second graft layers are not secured to each other being disposed between said first attached area and an edge of said first radial opening; a second attached area securing said first graft layer and said second graft layer together through a portion of said second radial opening (30b'), wherein a second unattached margin whereby said first and second graft layers are not secured to each other being disposed between said second attached area and an edge of said second radial opening; and wherein said first and second unattached margins are oriented along said first direction thereby allowing said first and second graft layers to move along said first direction relative to said stent (Column 3, proximate lines 42-45)

Regarding Claim 2, Lentz teaches the stent-graft assembly according to claim 1, wherein a size of said first attached area is less than a size of said first unattached margin (30a') and a size of said second attached area is less than a size of said second unattached margin (30b'), see fig. 3.

Regarding Claim 3, Lentz teaches the stent-graft assembly according to claim 1, wherein said first direction is axial (see fig. 3).

Regarding Claim 4, Lentz teaches the stent-graft assembly according to claim 1, wherein said first direction is circumferential (fig. 3).

Regarding Claim 5, Lentz teaches the stent-graft assembly according to claim 1, wherein said first attached area is positioned adjacent another edge of said first radial opening and said second attached area is positioned adjacent another edge of said second radial opening (fig. 3), said first and second attached areas being disposed on opposite sides of said first and second radial openings, whereby said first and second graft layers are restricted from moving along a second direction relative to said stent.

Regarding Claim 6, Lentz teaches the stent-graft assembly according to claim 5, wherein said first direction is axial and said second direction is circumferential (fig. 3)

Regarding Claim 7, Lentz teaches the stent-graft assembly according to claim 1, wherein said first attached area extends peripherally all around said first attached area and said second attached area extends peripherally all around said second attached area (fig. 3).

Regarding Claim 8, Lentz teaches the stent-graft assembly according to claim 7, wherein a size of said first attached area is less than a size of said first unattached margin (30a') and a size of said second attached area is less than a size of said second unattached margin (30b'), see fig. 3.

Regarding Claim 9, Lentz teaches the stent-graft assembly according to claim 1, wherein: a third unattached margin (30c') whereby said first and second graft layers are not secured to each other is disposed between said first attached area and an edge of said first radial opening; a fourth unattached margin whereby said first and second graft layers are not secured to each other is disposed between said second attached area and an edge of said second radial opening; and said third and fourth unattached

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margins are oriented along a second direction, thereby allowing said first and second graft layers to move along said second direction relative to said stent, said second direction being different than said first direction (fig. 3), it is noted that there is sufficient space in the unattached margins for the stent structure to move both longitudinally and circumferentially, see fig. 3.

Regarding Claim 10, Lentz teaches the stent-graft assembly according to claim 9, wherein a size of said first attached area (24') is less than a size of said third unattached margin and a size of said second attached area is less than a size of said fourth unattached margin (see fig. 3).

Regarding Claim 11, Lentz teaches the stent-graft assembly according to claim 1, wherein said first graft layer (22') covers substantially all of said luminal surface of said stent structure and said second graft layer (12') covers substantially all of said abluminal surface of said stent structure.

Regarding Claim 13, Lentz teaches the stent-graft assembly according to claim 1, wherein said first and second attached areas are attached by thermal bonding (Column 5, proximate lines 40-45).

Regarding Claim 14, Lentz teaches the stent-graft assembly according to claim 1, wherein said first and second graft layers comprise a synthetic polymer (Column 3, proximate lines 64-67).

Regarding Claim 16, Lentz teaches the stent-graft assembly according to claim 1, wherein said first and second attached areas are attached by thermal bonding

(Column 5, proximate lines 40-45); and said first and second graft layers comprise a synthetic polymer (Column 3, proximate lines 64-67).

Regarding Claim 17, Lentz teaches the stent-graft assembly according to claim 16, wherein: a third unattached margin whereby said first and second graft layers are not secured to each other is disposed between said first attached area and an edge of said first radial opening (30c'); a fourth unattached margin whereby said first and second graft layers are not secured to each other is disposed between said second attached area and an edge of said second radial opening; and said third and fourth unattached margins are oriented along a second direction, thereby allowing said first and second graft layers to move along said second direction relative to said stent, said second direction being different than said first direction (fig. 3), it is noted that there is sufficient space in the unattached margins for the stent structure to move both longitudinally and circumferentially, see fig. 3.

Regarding Claim 18, Lentz teaches the stent-graft assembly according to claim 17, wherein a size of said first attached area is less than a size of said first unattached margin and a size of said third unattached margin and a size of said second attached area is less than a size of said second unattached margin and a size of said fourth unattached margin (fig. 3).

Regarding Claim 19, Lentz teaches the stent-graft assembly according to claim 18, wherein said first graft layer (22') covers substantially all of said luminal surface of said stent structure and said second graft layer (12') covers substantially all of said abluminal surface of said stent structure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15 and 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz in view of Buirge et al. (US 2001/0034550).

Lentz teaches all limitations of preceding dependent claim 1 and claims 24-34, as previously described, but fails to teach wherein the graft layers comprise small intestine submucosa attached by thermal bonding. Buirge teaches a stent covered by two grafts, wherein the grafts are formed of submucosa attached by thermal bonding (paragraphs 53-60) in order to provide a graft material that can hold and release therapeutic material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lentz as taught by Buirge in order to provide a graft material that can hold and release therapeutic material.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz in view of Lombardi et al. (US6579314).

Lentz teaches all limitations of preceding dependent claim 1, but fails to teach wherein the first and second attached areas are attached using sutures. Lombardi teaches a covered stent having a luminal and abluminal covering sutured together (Column 5, proximate lines 27-30). It would have been an obvious matter of design choice to attach the graft members of Lentz with sutures as taught by Lombardi since applicant has not disclosed that suturing as opposed to welding serves any particular purpose or provides any advantage.

Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz in view of Buirge, and further in view of Lombardi. Lentz teaches all limitations of preceding dependent claims 1, 16 and 17, and further all limitations of claims 21-23 as described previously, but fails to teach wherein the graft layers comprise small intestine mucosa and are attached using sutures.

Regarding the limitation wherein the graft layers comprise small intestine mucosa, Buirge teaches a stent covered by two grafts, wherein the grafts are formed of submucosa attached by thermal bonding (paragraphs 53-60) in order to provide a graft material that can hold and release therapeutic material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lentz as taught by Buirge in order to provide a graft material that can hold and release therapeutic material.

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The combination of Lentz and Buirge fails to teach wherein the graft layers are attached using sutures. Lombardi teaches a covered stent having a luminal and abluminal covering sutured together (Column 5, proximate lines 27-30). It would have been an obvious matter of design choice to attach the graft members of Lentz with sutures as taught by Lombardi since applicant has not disclosed that suturing as opposed to welding serves any particular purpose or provides any advantage.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
10/18/06


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

10/20/06